

**Notice of Allowability**

Application No.

10/019,995

Examiner

Chih-Min Kam

Applicant(s)

ENDO ET AL.

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/27/04.
2. ☒ The allowed claim(s) is/are 1-11,13,15-21 and 23-29.
3. ☒ The drawings filed on 09 November 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20041214; 20050128</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____.   |

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ralph Webb on January 28, 2005.

**Examiner's Amendments to the Specification:**

Please replace the paragraph inserted after the title at page 1 in the preliminary amendment filed November 4, 2002 with the following paragraph:

The present application is a 371 of PCT/JP99/04088, filed July 29, 1999.

Please replace the term "Fig. 9 shows" at page 8, line 6 with "Figs. 9A, 9B and 9C show".

**Examiner's Amendments to the Claims:**

Claims 1-11, 13, 15-21 and 23-29 have been amended as follows:

1. (Currently amended) A preparation comprising a cell extract from the germ of flowering plants for cell-free protein synthesis prepared by substantially completely free of excluding all endosperm of said cell extract, thereby substantially excluding the systems involved in inhibiting the cell extract's protein synthesis reactions.

2. (Currently amended) A The preparation which contains cell extract for cell-free protein synthesis according to Claim 1, wherein substantially excluding said systems involved in inhibiting the cell extract's protein synthesis reactions comprises are substantially excluded by treating said cell extract with a nonionic surfactant.

3. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to Claim 2, wherein the cell extract is further treated by using ~~an acoustic wave~~ ultrasonication with said surfactant.

4. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to Claim 1, wherein the excluding of said systems involved in inhibiting the cell extract's protein synthesis reactions serves to control deactivation of ribosomes present in said cell extract.

5. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to Claim 1, wherein a substance is present ~~which to~~ controls deadenylation of ribosomes ~~characterized by excluding and to exclude~~ systems involving the inhibition of protein synthesis.

6. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to Claim 1, wherein the cell extract is from an embryo and said embryo is treated by adding nonionic surfactant and a substance controlling deadenylation of ribosome ~~by excluding to exclude~~ systems involving the inhibition of protein synthesis.

7. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 1, wherein said preparation can be stored in room temperature and ~~which~~ maintains biological functions of said cell extract.

8. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 7, wherein the preparation is in dried form.

9. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 8, wherein the preparation is formulated by freeze-drying.

10. (Currently amended) A method for ~~cell-free protein synthesis synthesizing a protein~~ in a cell-free system which is capable of recovering the synthesized ~~product~~ protein, said method comprising the steps of

providing a reaction vessel containing raw material substances that participate in cell-free protein synthesis, wherein the raw material substances ~~including~~ comprise the preparation of claim 1, and wherein the reaction vessel ~~includes~~ comprises a carrier capable of molecular sieving,

carrying out cell-free protein synthesis to obtain a synthesized ~~product~~ protein, during which synthesis the synthesized product protein is separated from the raw material substances by ~~differences in movement~~ moving through the carrier, and recovering the separated ~~synthesized product~~ protein.

11. (Currently amended) A method for ~~cell-free protein synthesis synthesizing a protein~~ in a cell-free system which is capable of recovering the synthesized ~~product~~ protein, said method comprising the steps of

providing a reaction vessel containing raw material substances that participate in cell-free protein synthesis, wherein the raw material substances ~~including~~ comprise the preparation of claim 1, and wherein the reaction vessel ~~includes~~ comprises a dialysis membrane that separates the reaction vessel into a reaction phase and an external phase, and

carrying out cell-free protein synthesis, during which synthesis the synthesized ~~product protein of the cell-free protein synthesis reaction~~ is produced in the reaction phase and is separated ~~into the external phase~~ from the raw material substances through the dialysis membrane, and

recovering the separated ~~synthesized product~~ protein.

13. (Currently amended) A preparation containing ~~cell extract~~ a cell extract for cell-free protein synthesis, comprising an extract of wheat embryo obtained ~~after~~ subjecting a treatment including a process for by washing the wheat embryo with

nonionic surfactant to completely remove any endosperm contaminants from the wheat embryo, ~~that a~~ wherein the deadenylation rate of the wheat extract is 1% or lower, and the dry preparation of the wheat embryo extract maintains stability ~~under~~ at room temperature; and ~~that~~ wherein said wheat extract is used in a continuous cell-free protein synthesis involving a replenishment of the substrate and other substances for protein synthesis ~~using said wheat extract,~~ and the synthesis shows constant performance even in 24<sup>th</sup> ~~twenty-fourth~~ hour after starting the synthesis and shows at least 1 mg/ml or higher in synthesis level in said 24<sup>th</sup> ~~twenty-fourth~~ hour.

15. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 2, wherein the ~~substantially~~ excluding of said systems involved in inhibiting the cell extract's protein synthesis reactions serves to control deadenylation of ribosome.

16. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 3, wherein the ~~substantially~~ excluding of said systems involved in inhibiting the cell extract's protein synthesis reactions serves to control deadenylation of ribosome.

17. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 2, wherein said preparation can be stored in room temperature and ~~which~~ maintains biological functions of said cell extract.

18. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 3, wherein said preparation can be stored in room temperature and ~~which~~ maintains biological functions of said cell extract.

19. (Currently amended) A The preparation ~~which contains cell extract for cell-free protein synthesis~~ according to claim 1, further comprising a synthesized substrate, an amino acid, an energy source, a surfactant, an ionic compound, or

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combinations thereof, wherein said preparation can be stored in room temperature and ~~which~~ maintains biological functions of said cell extract.

20. (Currently amended) A ~~The preparation which contains cell extract for cell-free protein synthesis~~ according to claim 5, wherein said preparation can be stored in room temperature and ~~which~~ maintains biological functions of said cell extract.

21. (Currently amended) A ~~The preparation which contains cell extract for cell-free protein synthesis~~ according to claim 6, wherein said preparation can be stored in room temperature and ~~which~~ maintains biological functions of said cell extract.

23. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis,  
wherein the raw material substances ~~including~~ comprise the preparation of claim 1, and  
carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

24. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis,  
wherein the raw material substances ~~including~~ comprise the preparation of claim 2, and  
carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

25. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis,  
wherein the raw material substances ~~including~~ comprise the preparation of claim 3, and

carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

26. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis, wherein the raw material substances including comprise the preparation of claim 4, and  
carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

27. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis, wherein the raw material substances including comprise the preparation of claim 5, and  
carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

28. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis, wherein the raw material substances including comprise the preparation of claim 6, and  
carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

29. (Currently amended) A method of synthesizing a protein in a cell-free system comprising the steps of  
providing raw material substances that participate in cell-free protein synthesis, wherein the raw material substances including comprise the preparation of claim 13, and  
carrying out cell-free protein synthesis in which the raw material substances participate to produce a synthesized protein.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

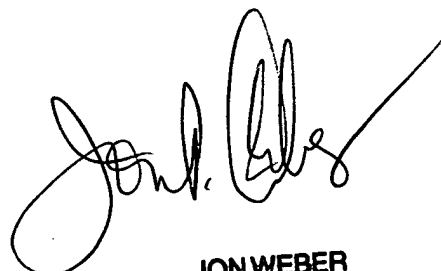
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CHK*  
Patent Examiner

CMK  
January 28, 2005



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**